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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,317	05/15/2002	Michael E. Selsted	P-UC 5042	6942

23601 7590 07/13/2005

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EXAMINER

DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,317

Applicant(s)

SELSTED ET AL.

Examiner

Anand U. Desai, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-22, 33-35, 51-67, 84-103, 106 and 109 is/are pending in the application.
- 4a) Of the above claim(s) 55-67 and 91-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-22, 33-35, 51-54, 84-90, 106 and 109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20050418</u> | 6) <input type="checkbox"/> Other: _____ |

J.O.O.

DETAILED ACTION

1. This office action is in response to Amendment filed on April 18, 2005. Claims 104, 105, 107, and 108 have been cancelled. Claims 15-22, 33-35, 51-54, 84-90, 106, and 109 are currently pending and are under examination.

Election/Restrictions

2. Applicants request for rejoinder of process claims 55-67, and 81-103 that depend from or otherwise include all the limitations of product is acknowledged. Product claims 15, and 19 are not indicated as patentable products, therefore the process claims are still withdrawn.

3. This application contains claims 55-67, and 81-103 drawn to an invention nonelected with traverse in paper filed April 18, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on April 18, 2005 is being considered by the examiner.

Withdrawal of Rejections

5. The rejection of claims 15-22 under 35 U.S.C. 101 is withdrawn based on Applicant's amendment to the claims.

6. The rejection of claims 15-22, 33-35, 51-54, 84-90, 106, and 109 under 35 U.S.C. 112, 2nd paragraph is withdrawn based on Applicant's amendment to the claims.

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Maintenance of Objections and Rejections

Specification

7. The disclosure is objected to because of the following informalities:
8. In the Brief Description Of The Drawing section: the description of figure 5 should identify panels A-F. Suggest, "Figures 5A-5F shows the coordinates used to generate the molecular model shown in Figure 4." The description of figure 13, appears to have a typographical error. Suggest, "(Figure 13A 14A; SEQ ID NO:24)...".

Appropriate correction is required.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 51-54, and 87-90 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 36, and 37 of U.S. Patent No. 6,890,537 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued U.S. Patent disclose a method of reducing or inhibiting growth or survival of a microorganism, comprising

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administering an effective amount of a theta defensin, wherein the theta defensin comprises the amino acid sequences identified as SEQ ID NO: 18 and 20. The claims of the current application claims a method of reducing or inhibiting growth or survival of a microorganism, administering theta defensin that comprise sequences identified as SEQ ID NO: 32, and 33. It would have been obvious to the person having ordinary skill in the art to use the sequences identified as SEQ ID NO: 32, and SEQ ID NO: 33, because Applicant's disclosure in U.S. Patent U.S. 6,890,537 B2 describes the state of the art required to identify theta defensin analogs. The analogs containing one or a few additions at selected positions in the theta defensin sequence will maintain broad spectrum antimicrobial activity (e.g. see col. 7, line 1 – col. 8, line 20). SEQ ID NO: 32 and 33 are amino acid sequences that comprise SEQ ID NO: 18, and 20; therefore SEQ IN NO: 32, and 33 are amino acid sequences that contain a few additions at selected positions in the theta defensin sequence.

11. Claims 15-22, 33-35, 51-54, and 84-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16, and 17 of copending Application No. 10/427,715 (US 2004/0014669 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to theta defensin polypeptides, pharmaceutical compositions comprising theta defensin polypeptides, method of reducing or inhibiting growth or survival of a microorganism comprising administering an effective amount of theta defensin, and the claims to the copending application are drawn to theta defensin polypeptides, pharmaceutical

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compositions comprising theta defensin polypeptides, method of reducing or inhibiting growth or survival of a microorganism comprising administering an effective amount of theta defensin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 15-22, 33-35, and 84-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 23-25 of U.S. Patent No. 6,335,318 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a theta defensin polypeptide comprising SEQ ID NO: 32, or 33, and a pharmaceutical composition comprising a theta defensin polypeptide, and the claims of U.S. Patent 6,335,318 B1 are drawn to an isolated theta defensin polypeptide, and pharmaceutical composition comprising theta defensin polypeptide. Claim 1 of U.S. Patent 6,335,318 B1 is drawn to a genus of theta defensin peptides. Applicant's disclosure in U.S. Patent U.S. 6,335,318 describes the state of the art required to identify theta defensin analogs (e.g. see col. 7, line 9 – col. 8, line 39). Therefore, it would have been obvious to the person having ordinary skill in the art to isolate the currently claimed theta defensin amino acid sequences and pharmaceutical compositions, because of the guidance provided. The currently claimed compositions would be encompassed by the claims of the issued U.S. Patent 6,335,318 B1.

13. Claims 106, and 109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,514,727 B1.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a method of expressing theta defensin polypeptide, and the claims of U.S. Patent 6,514,727 B1 are drawn to a method of expressing theta defensin polypeptide. Claim 1 of U.S. Patent 6,514,727 B1 is drawn to a genus of theta defensin peptides. Applicant's disclosure in U.S. Patent 6,514,727 B1 describes the state of art required to identify theta defensin analogs (e.g. see col. 7, line 11 – col. 8, line 41). Therefore, it would have been obvious to the person having ordinary skill in the art to express a theta defensin peptide currently being claimed because of the guidance provided describing theta defensin analogs. The currently claimed method would be encompassed by the method of claim 12 of issued U.S. Patent 6,514,727 B1.

Response to Remarks

14. Applicants request that the obviousness-type double patenting rejections be withdrawn. Applicants submit that claims 15-22, 33-35, and 84-86 of the current application could be viewed, at best, as directed to species of generic claims 1 and 23-25 of U.S. Patent 6,335,318, and therefore claims 15-22, 33-35, and 84-86 of the present application are unobvious over claims 1 and 23-25 of U.S. Patent 6,335,318. Applicants submit that claims 106, and 109 of the current application could be viewed, at best, as directed to species of generic claim 12, and therefore claims 106, and 109 of the present application are unobvious over claim 12 of U.S. Patent 6,514,727. Applicant's arguments filed April 18, 2005 have been fully considered but they are not persuasive. Applicant's disclosure in U.S. Patent U.S. 6,335,318 describes the state of the art required to identify theta defensin analogs (e.g. see col. 7, line 9 – col. 8, line 39). It

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would have been obvious to the person having ordinary skill in the art to isolate the currently claimed theta defensin amino acid sequences and pharmaceutical compositions, because of the guidance provided to identify theta defensin peptides with antimicrobial activity. Furthermore, it would have been obvious to the person having ordinary skill in the art to use the method of expressing a theta defensin as disclosed in claim 12 of U.S. Patent 6,514,727 to claim a method of expressing the currently claimed theta defensin.

Conclusion

15. No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

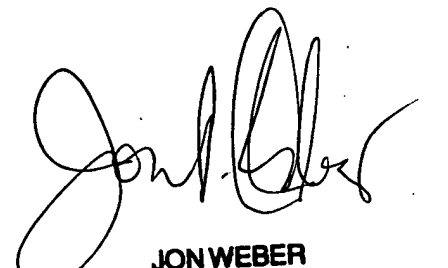
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 2, 2005

A handwritten signature in black ink, appearing to be 'M. Dai'.A handwritten signature in black ink, appearing to be 'Jon Weber'.

JON WEBER
SUPERVISORY PATENT EXAMINER